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<b>(54) Title:</b> EDIBLE FAT-CONTAINING PRODUCTS CONTAINING VITAMIN E  <b>(57) Abstract</b>  The present invention pertains to edible fat-containing products comprising an indigestible fat-replacer and vitamin E at a level of above 2.9 mg vitamin E per gram of indigestible fat-replacer.		

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<sup>+</sup> Any designation of "SU" has effect in the Russian Federation. It is not yet known whether any such designation has effect in other States of the former Soviet Union.

EDIBLE FAT-CONTAINING PRODUCTS  
CONTAINING VITAMIN E

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The present invention relates to edible fat-containing products comprising an indigestible fat-replacer and vitamin E.

10 In this specification, unless otherwise indicated, the term 'fat' refers to edible fatty substances in a general sense, including natural or synthesized fats and oils consisting essentially of triglycerides such as, for example, soybean oil, sunflower oil, palm oil, coconut oil, fish oil, lard  
15 and tallow, which may have been partially or completely hydrogenated or modified otherwise, as well as non-toxic fatty materials having properties similar to triglycerides, herein referred to as fat-replacers, which materials may be partially or fully indigestible. The terms fat and oil are  
20 used interchangeably.

Over the last decade many non-triglyceride fatty substances have been described as potential fat-replacers in food products. Examples thereof are waxes, e.g. jojoba oil and  
25 hydrogenated jojoba oil, polysiloxanes, acylated glycerides, polyalkoxyglycerolethers, dicarboxylic acid esters, polyol fatty acid polyesters and the epoxy extended derivatives thereof. Examples of disclosures of fat-replacers are e.g. DD 207 070, Journal of Food Science 49,  
30 419-428 (1984), US 3,600,186, US 4,005,195, US 4,005,196, US 4,034,083, US 4,582,715, US 4,582,927, EP 0 233 856, EP 0 236 288, EP 0 235 836 and EP 0 254 547.

In particular polyol fatty acid polyesters, and more  
35 specifically the sugar fatty acid polyesters, such as e.g. the sucrose fatty acid polyesters, are receiving increased attention as low-calorie fat-replacers in edible products.

Substantially indigestible for human beings they have physical and organoleptic properties very similar to triglyceride oils and fats conventionally used in edible products.

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Polyol fatty acid polyesters are also reported to have use as pharmaceutical agents e.g. in view of their ability to take up fat-soluble substances, such as in particular cholesterol, in the gastro-intestinal tract, and subsequently remove those substances from the human body.

10

In US 4,005,196 and US 4,034,083 indigestible sucrose fatty acid polyesters in the diet are reported to interfere with the absorption of the fat-soluble vitamins A, D, E and K.

15

It is taught to overcome possible vitamin mal-absorption effects by fortifying the sucrose fatty acid polyester containing food compositions with fat-soluble vitamins.

20

An important fat-soluble vitamin occurring in many vegetable oils such as in particular, corn, cottonseed, peanut, safflower, sunflower, soybean and wheat germ oils, is vitamin E. Vitamin E is the collective name for a group of eight compounds all having to some extent the biological activity which is characteristic to vitamin E. Four members

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of this group are formed by the tocopherols, i.e. alpha-, beta, gamma- and delta-tocopherol, differing from each other only with respect to the methyl position on the benzene ring. Each of the tocopherols have a number of stereomers in view of the presence of three asymmetric

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carbon atoms. Further members of the group of vitamin E compounds are formed by the tocotrienols, which are similar to the corresponding tocopherols but with unsaturated side chains. The most abundant and, in terms of vitamin E activity most potent, member of the vitamin E compounds is

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alpha-tocopherol.

The form in which vitamin E is present in conventional food products is either as one or more of the in nature occurring compounds of the vitamin E group or as the commercially readily available and very stable acetic acid ester of vitamin E, in particular  $\alpha$ -tocopheryl acetate. In this specification the term vitamin E is intended to collectively refer to the above group of natural compounds having the biological activity characteristic for vitamin E, and the short-chain organic acid esters of vitamin E, in particular  $\alpha$ -tocopheryl acetate.

Although no fixed minimum daily requirements of vitamin E can easily be given, recommended dietary allowances for adults in most countries are in the range of 10 to 15 mg per day.

Substitution of the conventional absorbable fat or oil components in food products by an indigestible fat-replacer results in a reduction of the vitamin E absorption which is not only due to the interference by the indigestible fat-replacer with the absorption of vitamin E as supplied by various food sources, but also due to a reduction of the vitamin E supply itself in the food resulting from substitution of e.g. vegetable oils by fat-replacers which do not contain vitamin E.

Although depletory effects by indigestible fat-replacers in the diet are believed to depend on a multiplicity of dietary factors, in the art to date only low levels of vitamin E per gram of fat-replacer in the diet have been described.

It has now been found that indigestible fat-replacers, and in particular, indigestible polyol fatty acid polyesters, even in relatively low fat-replacement levels may have depletory effects which cannot, in all dietary circumstances, be fully compensated by fortification levels

of vitamin E hitherto believed to be sufficient. In particular, it has been found that levels of vitamin E fortification must lie above 2.9 mg more preferred above 3 mg per gram of indigestible fat-replacer in the diet to  
5 ensure at the full range of fat-replacement levels sufficient vitamin E suppletion to maintain liver vitamin E levels equal to those resulting from normal indigestible fat-replacer free diets.

10 Accordingly, in its broadest aspects the present invention provides edible fat-containing products comprising an indigestible fat-replacer and vitamin E at a level of above 2.9 mg, more preferred above 3 mg vitamin E per gram of indigestible fat-replacer.

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Preferably the vitamin E used at the levels as indicated above is a short chain organic acid ester of vitamin E, most preferred is the use of vitamin E acetate, for example  $\alpha$ -tocopheryl acetate.

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Vitamin E acetate is a particularly advantageous form of vitamin E, because it is available at a low price, easy to handle and stable. However, particularly when vitamin E acetate is used, relatively high levels of this material  
25 such as presently claimed are necessary for preventing depletory effects.

The indigestible fat-replacer may be any indigestible fatty material which in physical properties and rheology behaves  
30 similar to conventional triglyceride oils and fats. Examples thereof have been given hereinbefore.

In this specification by 'indigestible' is meant that about 70% by weight or more of the material concerned is not digested by the human body.

- 5 A preferred class of indigestible fat-replacers for inclusion in the edible fat-containing products of the invention are the polyol fatty acid polyesters.

Suitable polyol fatty acid polyesters are derived from  
10 aliphatic or aromatic polyols which comprise at least four free hydroxyl groups. Such polyols in particular include the group of sugar polyols, which comprises the sugars, i.e. the mono-, di- and polysaccharides, the corresponding sugar alcohols and the derivatives thereof having at least  
15 four free hydroxyl groups. Examples of sugar polyols include glucose, mannose, galactose, xylose, fructose, sorbose, tagatose, ribulose, xylulose, maltose, lactose, cellobiose, raffinose, sucrose, erythritol, mannitol, lactitol, sorbitol, xylitol and alpha-methylglucoside. A  
20 particularly preferred polyol is sucrose.

The term 'polyol fatty acid polyester' is intended to refer to any such polyesters or mixtures thereof which have a degree of conversion of 70 % or more, i.e. of which, on an  
25 average, 70 % or more of the polyol hydroxyl groups have been esterified with fatty acids. Preferred polyol fatty acid polyesters for use in the present invention have degrees of conversion of 85 % or more, or even 95 % or more.

30

The fatty acid residues in the polyol fatty acid polyesters may be derived from naturally occurring or synthetic fatty acids per se, or suitable sources thereof, such as natural triglyceride fats and oils or their corresponding lower-  
35 alkyl esters. The fatty acids may be saturated or unsaturated, branched or straight fatty acids containing from 8 to 24 carbon atoms, in particular 12 to 18 carbon

atoms, such as lauric, myristic, palmitic, stearic, oleic, elaidic, and linoleic acids. Suitable natural sources are the vegetable oils, such as sunflower, safflower, rapeseed, palm kernel, palm and soybean oils. If so required, conventional techniques may be used to first introduce the necessary degree of saturation. Suitable such techniques include full or partial hydrogenation, interesterification, and fractionation, and may be used before or after conversion to the polyol fatty acid polyesters.

10 The fat component in the compositions of the invention may consist solely of a single indigestible fat-replacer, but may also be a mixture of different indigestible fat-replacers or a mixture of indigestible fat-replacers and conventional triglyceride fats. Generally, at least 10 % by weight of the fat component of the edible compositions will consist of indigestible fat-replacer. However, in view of calorie reduction it is preferred that of from 50 % up to 90 or even 100 % of the fat component consists of the indigestible fat-replacer.

The optional conventional fat-component may be triglyceride oils or fats of animal or vegetable origin. Suitable conventional triglyceride fats and oils include, optionally partially or fully hydrogenated, coconut oil, palmkernel oil, palm oil, marine oils, lard, tallow fat, butter fat, cocoa butter fat, soybean oil, safflower oil, cotton seed oil, rapeseed oil, corn oil sunflower oil and mixtures thereof.

30 In terms of rheology the selection of the appropriate fat-replacer or mixture of fat-replacer and conventional fat strongly depends upon the particular application envisaged, and may range of fat-replacers having a fully fluid rheology to replace liquid oils in e.g. salad, frying or seasoning oils, to more viscous or even solid rheology in compositions having a more structured fat phase such as



margarines, spreads, shortenings and confectionery products.

The required rheology and melting behaviour may be  
5 optimised to specific applications both by selection of an appropriate blend of fatty acids and/or selection of an appropriate blend of fat-replacers with different rheologies. If significant amounts of indigestible liquid fat-replacers are included it is often advantageous also to  
10 include certain amounts of hard-stock fatty material, either conventional solid fats or solid fat-replacer, and/or dietary fibre materials, to avoid too strong laxative or even anal-leakage effects.

15 The essential feature of the present invention is fortification with vitamin E at levels of above 2.9 or above 3 mg vitamin E per gram of indigestible fat-replacer. Conventional levels of vitamin E do not guarantee that the liver vitamin E status is maintained at a level  
20 corresponding to normal dietary vitamin E intakes at the full range of the indigestible fat-replacer substitution levels.

Suitable fortification levels range from 2.9 to 10 mg  
25 vitamin E per gram of the indigestible fat-replacer in the composition, and in particular, from 3.5 to 7 mg per gram. Preferred fortification levels lie within the range of from 3.5 to 5.5 mg per gram of indigestible fat-replacer.

30 The present invention is not specific to edible fat-containing compositions in any particular food area. It may be suitably be applied to food products such as spreads, margarines, creams, salad oils, frying oils, shortenings, bakery products such as doughs, cakes and biscuits, fried  
35 and snack products, fresh, hard and processed cheeses, meat emulsions, mayonnaise and dressings, confectionery

products, such as desserts, fillings, chocolates, candies, chews, and ice-creams.

Example I

To illustrate the invention there were carried out a series of examples to show the effect of various levels of indigestible fat replacer and vitamin E.

5

The experiments involved 3 weeks' feeding trials of groups of 8 rats in which the vitamin E status of the liver was determined after three weeks.

10 Materials used:

- (1) fat-replacer: SPE sucrose fatty acid polyesters (degree of conversion above 95%) in which the fatty acid residues are derived from touch-hardened soybean oil (IV = 107).
- (2) vitamin E source: dl- $\alpha$ -tocopheryl acetate, type CWS, Roche 500 IU/g
- (3) diet information (see tables 2-4).

20 Table 2

Composition of the purified basic diet (g/1000Kcal)

25	Ingredients:	Calcium Caseinate	60.7
		Mineral mixture	3.6
		Vitamin mixture	3.6
		Maize starch	162.9
		Lard	17.2
		Sunflower seed oil	4.3
30		Solkafloc UF-900	30.0
		SPE	variable (see table I)

Table 335 Composition of the mineral mixture (mg/1000Kcal)

	Potassium chloride	KCl	350.0
	Sec. magnesium phosphate	MgHPO <sub>4</sub> ·3H <sub>2</sub> O	956.0
	Prim. potassium phosphate	KH <sub>2</sub> PO <sub>4</sub>	475.0
40	Potassium bicarbonate	KHCO <sub>3</sub>	719.0
	Calcium carbonate	CaCO <sub>3</sub>	295.0
	Trisodium 2 hydrate	C <sub>6</sub> H <sub>5</sub> Na <sub>3</sub> O <sub>7</sub> ·2H <sub>2</sub> O	711.0
	Manganese sulphate	MnSO <sub>4</sub> ·H <sub>2</sub> O	51.4
	Ferric (III) citrate	C <sub>6</sub> H <sub>5</sub> FeO <sub>7</sub> ·5H <sub>2</sub> O	43.9
45	Copper citrate	Cu <sub>2</sub> C <sub>6</sub> H <sub>6</sub> O <sub>8</sub> ·H <sub>2</sub> O	4.7
	Zinc citrate	Zn <sub>2</sub> C <sub>6</sub> H <sub>6</sub> O <sub>8</sub>	12.5
	Potassium iodate	KIO <sub>3</sub>	0.07

Table 4

Composition of the vitamin mixture (mg/1000Kcal)

5	Choline chloride	(50%)	500.0
	Myo-inositol		25.0
	Calcium silicate		50.0
	Ca-pantothenic acid		5.0
10	Niacin		5.0
	Biotin		0.05
	Vitamin A	325 IU/mg	7.7
	Vitamin B-1		1.5
	Vitamin B-2		1.5
15	Vitamin B-6		0.5
	Vitamin B-12	1000 mg/kg	5.0
	Vitamin D-3	80 IU/mg	3.1
	Vitamin K-3	22,7%	1.0
	Folic acid		0.25
20	Vitamin E	variable (see table 1)	
	Saccharose		

Vitamin E acetate (IU) requirement per gram SPE in the diet of rats

Table V

	SPE in diets of rats		Liver vitamin E status of rats  μg/g	Vitamin E acetate in diet to reach liver status  IU/1000Kcal	Vitamin E acetate (IU) requirement per gram SPE
	g/1000Kcal	w/w%			
30	0.0	0.0	20	4.9	-
35	2.5	0.9	20	16.3	4.5
	5.0	1.8	20	22.9	3.6
	10.0	3.5	20	35.4	3.0
	20.0	6.7	20	62.2	2.9
	30.0	9.7	20	92.6	2.9
40	0	0	25	7.2	-
	2.5	0.9	25	24.0	6.7
	5.0	1.8	25	33.7	5.3
	10.0	3.5	25	52.1	4.5
45	20.0	6.7	25	91.2	4.2
	30.0	9.7	25	135.7	4.3
50	0	0	30	9.9	-
	2.5	0.9	30	32.8	9.2
	5.0	1.8	30	46.0	7.2
	10.0	3.5	30	71.2	6.1
	20.0	6.7	30	124.4	5.7
	30.0	9.7	30	185.3	5.8

Vitamin E acetate = dl-α-toc pheryl acetate (1 mg = 1 IU)

For various levels of SPE in the diet the required vitamin E level was determined for reaching a liver vitamin E status of 20-30  $\mu\text{g/g}$ .

- 5 The results are represented in table V. These results illustrate that vitamin E levels of at least 2.9 mg per gram SPE are required to obtain a liver status of 20  $\mu\text{g/g}$ . Levels of at least 3 mg per gram SPE, for example 3-10 mg generally provide satisfactory vitamin E levels in the
- 10 liver.

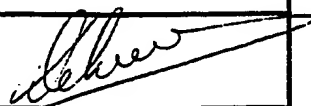
Claims.

1. Edible fat-containing product which comprises an  
5 indigestible fat-replacer and vitamin E at a level of at  
least 2.9 mg vitamin E per gram of indigestible fat-  
replacer.
2. Edible fat containing product according to claim 1,  
10 comprising from 3 to 10 mg vitamin E per gram of  
indigestible fat-replacer.
3. Edible fat containing product according to claim 1 or  
2, wherein the vitamin E is a short chain organic acid  
15 ester of vitamin E.
4. Edible fat containing product according to claims  
1-3, wherein the vitamin E is vitamin E acetate.
- 20 5. Edible fat containing product according to claim 4,  
wherein the vitamin E is an  $\alpha$ -tocopheryl acetate.
6. Edible fat containing product according to claim  
1-5 wherein the indigestible fat replacer is an  
25 indigestible polyol fatty acid polyester.
7. Edible fat containing product according to claim 6,  
wherein at least 85% of the polyol hydroxyl groups have  
been esterified with fatty acids.
- 30 8. Edible fat containing product according to claims  
6-7, wherein the polyol is a sugar polyol.
9. Edible fat containing product according to claim 8,  
35 wherein the sugar polyol is sucrose.

## INTERNATIONAL SEARCH REPORT

PCT/EP 91/02179

International Application No

<b>I. CLASSIFICATION OF SUBJECT MATTER</b> (If several classification symbols apply, indicate all) <sup>6</sup>		
According to International Patent Classification (IPC) or to both National Classification and IPC		
Int.Cl. 5 A23D9/00;                      A23L1/302;                      A23L1/308		
<b>II. FIELDS SEARCHED</b>		
Minimum Documentation Searched <sup>7</sup>		
Classification System	Classification Symbols	
Int.Cl. 5	A23D ;                      A23L	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched <sup>8</sup>		
<b>III. DOCUMENTS CONSIDERED TO BE RELEVANT<sup>9</sup></b>		
Category <sup>10</sup>	Citation of Document, <sup>11</sup> with indication, where appropriate, of the relevant passages <sup>12</sup>	Relevant to Claims No. <sup>13</sup>
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X	US,A,4 005 196 (RONALD JAMES JANDACEK ET AL.) 25 January 1977 cited in the application see column 10, line 48 - line 63; claims 1,21,26 see column 11, line 4 - line 53 see column 12, line 38 - column 13, line 34 ---	1-9
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-/-		
<p><sup>10</sup> Special categories of cited documents:</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"A" document member of the same patent family</p>		
<b>IV. CERTIFICATION</b>		
Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report	
28 JANUARY 1992	11. 02. 92	
International Searching Authority	Signature of Authorized Officer	
EUROPEAN PATENT OFFICE	DEKEIREL M.J. 	

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)		Relevant to Claim No.
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A	EP,A,0 354 600 (UNILEVER NV) 14 February 1990 see the whole document ---	1-9



**ANNEX TO THE INTERNATIONAL SEARCH REPORT**  
**ON INTERNATIONAL PATENT APPLICATION NO. EP 9102179**  
SA 53203

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on  
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